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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,859	08/16/2000	Leonard S. Girsh	5163*3	2441

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IP DEPARTMENT OF PIPER RUDNICK LLP
ONE LIBERTY PLACE, SUITE 4900
1650 MARKET ST
PHILADELPHIA, PA 19103

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/639,859	GIRSH, LEONARD S.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *45-79 and 96-100*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See attached Interview Summary*

Continuation of 2. NOTE: The amendment filed August 6, 2004 does not resolve the current issues under 35 USC 112, first and second paragraphs, it also raise new issues regarding the molar ratio of L-amino acids of blood (new claim 102), which requires further consideration because the specification indicates the cited molar ratio is the ratio for fibrinogen (page 12, last paragraph), not the claimed blood. In the amendment of August 6, 2004, claims 45, 59, 97, 98 and 100 have been amended, and new claims 101-103 have been added. The Declaration of Dr. Lenoard Girish filed August 6, 2004 and applicants' response have been fully considered, however, claims 45-77 and 96-100 remain rejected under 35 USC 112, first and second paragraphs.

If applicants' amendment were entered, it would have the following response:

1. Claims 45-77 and 96-103 are rejected under 35 USC 112, first paragraph, see paragraph 6 in the previous Office Action dated March 5, 2004. In response, applicants indicate that the molar ratio of amino acids in a given tissue can differ from that in other tissues. This amino acid ratio can be readily determined by one skilled in the art without undue experimentation, by following the teachings of the specification and applying the knowledge possessed by the skilled person, e.g., the section of Individualized Therapy (pages 32-34) indicates diseased tissue may be analyzed and compared with healthy adjacent tissue to determine the nutrients needed; the specification identifies useful therapeutic applications for specific L-amino acids in Table 1 (page 22); case 2 of the working examples (page 39) show the prophetic treatment of an adult female kidney transplant with a medicament of the invention; and the Declaration of Dr. Lenoard Girish further show the actual treatment of a 71-year old female patient suffering from Crohn's disease by administering a medicament according to the present invention; claims 59, 60, 75, 99 and 100 specify the L-amino acid ratios in the claimed medicament being that of cyclosporin, and new claim 103 specify the damaged tisse, and one skilled in the art could readily determine the L-amino acid molar ratio required to make the the claimed medicaments for treating damage to these tissues (pages 9-16 of the response). The response has been considerd, however, the argument is not found persuasive because the specification does not demonstrate the use of molar ratio of L-amino acids of a healthy tissue in the treatment of the same tissue being damaged, e.g, case 2 is related to a patient with kidney disease, however, the treament only indicates the use of essential L-amino acids, it does not indicate the molar ratio of L-amino acids comes from a healthy tissue of kidney; and the Declaration indicates a patient of Crohn's disease (a disease of small intestine and large intestine) is treated with molar ratio of amino acids of a human tissue (e.g., breast milk and stem cell human tissue). Thus, the identification and use of molar ratio of L-amino acids of a specific healthy tissue in the treatment of a damaged tissue requires undue experimentation because further research is needed to identify the healthy tissue used and further to determine the molar ratio of amino acids of this specific healthy tissue needed for the treatment and its therapeutic effect. Note that the specification does not disclose the molar ratio of amino acids in claim 102 is for blood, it is the molar ratio of fibrinogen which is a peptide, not a tissue; and cyclosporin (a cyclic peptide) is a drug, not a healthy tissue.

2. Claims 45-77 and 96-103 are indefinite because of the use of the term "the amino acis being present at a molar ratio which is characteristic of healthy tissue of the type of tissue being treated for damage". The cited term renders the claim indefinite, it is unclear what healthy tissue is referred to, and what is the characteristic amino acid molar ratio of the healthy tissue. Claims 46-77 and 96-103 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate amino acid ratio in the claimed medicaments will vary from tissue to tissue, the skilled artisan can readily determine the amino acid ratio of the healthy tissue and diseased tissue (pages 8-9 of the response). The argument is not persuasive because the healthy tissue is not identified in the claim, it is not clear what is the molar ratio of the amino acid components for the healthy tissue.

3. Claims 56, 57 and 61-64 are indefinite because of the use of the term "said aliphatic side chain is a short chain fatty acid". The term cited renders the claim indefinite, it is unclear how can the aliphatic side chain, which does not have a carboxylic acid group, be a short chain fatty acid since the claim refers ammoniated short chain fatty acid such as gamma amino butyric acid as an amino acid. Claims 57 and 61-64 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend. In response, applicants indicate a fatty acid which is an open chain compound can be aliphatic regardless of the presence of a carboxylic acid group (pages 9-10 of the response). The argument is not persuasive because the claim refers ammoniated short chain fatty acid such as gamma amino butyric acid as an amino acid, thus the aliphatic side chain, which is part of amino acid without carboxyl group, can only be a short chain of fatty acid, not a short chain fatty acid.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 97, 98 and 100 under 35 USC 112, second paragraph .

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issues under 35 USC 112, first and second paragraphs .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
August 25, 2004

Jon P. Weber, Ph.D.
Primary Examiner